



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Science Review in Support of the Registration of Bedoukain Z-11-Hexadecenyl Acetate Technical Pheromone (EPA File Symbol No. 052991-RL) containing 95.0% Z-11-Hexadecenyl Acetate (Chemical No. 129071) as a New Active Ingredient. Review of Product Chemistry Studies. DP Barcode D273380; Case No. 069004; Submission No. S595305; MRID No. 453285-01.

FROM: Russell S. Jones, Ph.D., Biologist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

THRU: Freshteh Toghol, Ph.D., Senior Scientist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

TO: Andrew Bryceland, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

ACTION REQUESTED

In response to a request for additional information (see Memorandum from R. S. Jones to A. Bryceland, dated 12/06/2000), Bedoukian Research, Inc. submitted additional product chemistry data/information for the TGAI/MP product, Bedoukain Z-11-Hexadecenyl Acetate Technical Pheromone (EPA File Symbol. No. 52991-RL) containing 95% Z-11-hexadecenyl acetate as its active ingredient. In support of the registration, the registrant has submitted data/information pertaining to the manufacturing process, certified limits, and analytical methods (MRID No.453285-01), as well as a revised Confidential Statements of Formula (CSF; dated 02/08/2001) for the basic formulation, and a revised label.

CONCLUSIONS AND RECOMMENDATIONS

1. The submitted supplementary product chemistry data are acceptable to support the registration of Bedoukian Z-11-Hexadecenyl Acetate Technical Pheromone (EPA File Symbol. No. 52991-RL) pending resolution of the CSF deficiencies described in Conclusions 2 and 3.
2. [REDACTED]
3. The CSF for the basic formulation is unacceptable, but upgradable. To upgrade the CSF to acceptable, the registrant must submit lower certified limits for [REDACTED]
[REDACTED]
[REDACTED].

STUDY SUMMARY

Product Chemistry

The registrant submitted product chemistry data/information on the manufacturing process, certified limits, and analytical methods, as well as a revised CSF (dated 02/08/2001), and a proposed label for Bedoukian Z-11-Hexadecenyl Acetate Technical Pheromone (EPA File Symbol. No. 52991-RL). The registrant states that [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] The registrant submitted an acceptable explanation for not submitting a analytical method limit of detection.

CLASSIFICATION: Acceptable resolution of the deficiencies detailed in Conclusions 2 and 3 above.

cc: F. Toghrol, R. S. Jones, A. Bryceland, BPPD Subject File
R. S. Jones: F T. CM2, (703) 308-5071; 03/21/2001

THE FOLLOWING PAGES CONTAIN CONFIDENTIAL BUSINESS INFORMATION

DATA EVALUATION REPORT

Reviewed by: Russell S. Jones, Ph.D. BPPD

Secondary Reviewer: Freshteh Toghrol, Ph.D. BPPD

STUDY TYPE: Product Chemistry (Subdivision M Guidelines 151-10 to 151-17)

DP BARCODE: D273380

CASE No. 069004

SUBMISSION No.: S593305

PC CODE: 129071

TOX. CHEM. No.: None

MRID Nos: 453285-01

TEST MATERIAL: Bedoukian Z-11-Hexadecenyl Acetate Technical Pheromone
(containing 95% active ingredient)

STUDY Nos: None

SPONSOR: Bedoukian Research, Inc., 21 Finance Drive, Danbury, CT 06810-4192

TESTING FACILITY: Bedoukian Research, Inc., 21 Finance Drive, Danbury, CT 06810-4192

TITLES OF REPORTS: Supplemental Product Chemistry for Bedoukian Z-11-Hexadecenyl Acetate Technical Pheromone - Addendum to MRID 451518-01

AUTHOR: Robert E. Mahoney

REPORTS ISSUED: February 7, 2001

QUALITY ASSURANCE: The product chemistry study was not conducted under Good Laboratory Practice (GLP) standards, but standards at the performing laboratory followed the intent of the GLPs. Non-compliance statements in were signed by sponsor/submitter (A. P. Roberts) on 02/07/2001.

SUMMARY: The registrant submitted product chemistry data/information on the manufacturing process, certified limits, and analytical methods, as well as a revised CSF (dated 02/08/2001), and a proposed label. The registrant states that [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

The registrant submitted an acceptable explanation for not determining the analytical method limit of detection for this pheromone product.

CLASSIFICATION: Acceptable, pending submission of : (i) a CSF for an alternate formulation [REDACTED]; and (ii) a CSF for the basic formulation [REDACTED]

I. MANUFACTURING PROCESS (151-11)

In the original manufacturing process data/information submission (MRID 451518-01; see Memorandum from R. S. Jones to A. Bryceland, dated 12/06/2000), [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

In the latest submission (MRID 453285-01), the registrant states that [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

II. CERTIFICATION OF INGREDIENTS (151-15)

In the original submission (MRID 451518-01), the registrant stated that the certified limits for the active and inert ingredients were determined by [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Ingredient*	% by weight*	Certified Limits (% by weight)*	
		Upper	Lower
Z-11-Hexadecenyl Acetate	95.00		

*from CSF dated 02/08/2001

In a reiteration of the discussion presented above in the Manufacturing Process section:

In the latest submission (MRID 453285-01), the registrant states that [REDACTED]
[REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED] [REDACTED]

III. ANALYTICAL METHODS (151-16; OPPTS 830.1800)

The registrant did not submit a limit of detection (LOD) for its analytical method. An LOD was requested in the previous review of the data (see Memorandum from R. S. Jones to A. Bryceland, dated 12/06/2000). An LOD for the analytical method(s) is(are) routinely requested by BPPD of all registrants of TGA/MP products. The registrant provided a detailed explanation of why (in their opinion) an LOD determination would not be practical for their pheromone TGA/MP. This explanation (see attachment) is acceptable. No additional data are required.

Fax 202 872-0745

- c. **Analytical Method.** EPA stated that the analytical method is acceptable pending submission of an acceptable limit of detection. The enclosed addendum to MRID No. 451518-01 states that no limit of detection is provided for the analytical method. The reason for not providing a limit of detection is as follows:

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- It is the experience of Bedoukian Research, Inc. that determining limits of detection for the analytical method, for pheromone active ingredients, is not practical or necessary. At present, Bedoukian Research, Inc. is registrant of thirteen technical grade pheromone active ingredients, and to date, Bedoukian has not provided limits of detection for the analytical methods of any of those registered pheromones.

- A method of limit detection would be necessary and applicable for a product that is a high dilution of a substance in a solvent. For example, if an end-use formulation of Bedoukian (Z)-11-Hexadecenyl Acetate Technical Pheromone consisted of an emulsion of the technical pheromone in a sprayable formulation, a method of limit detection would be appropriate in order to verify the actual active ingredient level in the final product. Bedoukian (Z)-11-Hexadecenyl Acetate is not such a product. It is a manufacturing-use product that [REDACTED] active ingredient.

- The chromatograms provided in the product chemistry volume (MRID No. 451518-01) illustrate the peak height and areas of the active ingredient. Other than the solvent used for sample preparation, which is not integrated in the chromatogram's reports, the active ingredient is the most predominant peak. In our opinion, it is not practical to provide a method of limits of detection for a neat material such as this pheromone. If the active ingredient content of the product is within the certified limits, [REDACTED],

and this will chromatographically resemble the already submitted data.

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